July 24, 2002

Natalie Rutherford
FMC Corporation
1735 Market Street
Philadelphia, PA 19103

Dear Ms. Rutherford:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for methyallyloxyphenol, posted on the ChemRTK HPV Challenge Program Web site on February 5, 2002. I commend the FMC Corporation for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its HPV Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the attached Comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that FMC Corporation advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the HPV Challenge Program Web site "Submit Technical Questions" button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Attachment

cc: W. Sanders
A. Abramson
C. Auer
M. E. Weber

EPA Comments on Chemical RTK HPV Challenge Submission:
Methyallyloxyphenol

SUMMARY OF EPA COMMENTS

The sponsor, FMC Corporation, submitted a test plan and robust summaries to EPA for Methyallyloxyphenol (MOP) (CAS #4790-71-0) dated December 28, 2001. EPA posted the submission on the ChemRTK HPV Challenge Web site on February 5, 2002.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical and Environmental Fate Data. EPA agrees with the submitter's proposal to conduct partition coefficient, water solubility, hydrolysis, and biodegradation tests. All other appropriate SIDS-level tests/estimations have been performed and adequate robust summaries have been submitted.

2. Health Endpoints. EPA agrees that MOP meets the criteria for a "closed system intermediate." Thus, only the developmental toxicity study needs to be performed (deferred until 2003).

3. Ecotoxicity. All appropriate SIDS-level tests have been performed and adequate robust summaries have been submitted. However, the submitter needs to provide a missing data element.

EPA requests that the Submitter advise the Agency within 60 days of any modifications to its submission.

EPA COMMENTS ON METHYLALLYLOXYPHENOL CHALLENGE SUBMISSION

Test Plan

Chemistry (melting point, boiling point, vapor pressure, water solubility, and partition coefficient).

EPA agrees with the submitter's proposal to conduct partition coefficient and water solubility tests. Adequate existing data are available for the other endpoints.

Environmental Fate (photodegradation, stability in water, biodegradation, and transport/distribution).

EPA agrees with the submitter's proposal to conduct hydrolysis and biodegradation tests. Adequate existing data are available for the other endpoints. However, the submitter needs to provide the in-put values for the fugacity calculation.

Health Effects

The submitter proposes to conduct a developmental toxicity study (deferred until 2003). Adequate data are available for the acute and genetic toxicity endpoints. The submitter notes that neither repeated dose toxicity nor reproductive toxicity data are needed because MOP is a "closed system intermediate" as defined by EPA for the HPV Challenge Program.

Reproductive and Repeat Dose Toxicity

The Guidance for Testing Closed System Intermediates for the Challenge Program http://www.epa.gov/chemrtk/guidocs.htm allows for a reduced testing proposal provided certain criteria are met. The information required to judge a "closed system intermediate" claim must address the following:

I. Site information.
    A. Number of sites.
    B. Basis for "closed process" conclusion at each site.
        1) Process description.
        2) Monitoring data showing no detection.
        3) In the absence of monitoring data, the basis for believing that releases do not occur.
    C. Data on "presence in distributed products."
II. Information on transport (mode, volume, controls, etc.)
III. A data search showing that the chemical is not present in other endproducts.

EPA believes that the submitter has adequately addressed the criteria described above. MOP is produced at a single site, is consumed in the in-process reaction to make another substance, and there are no off-site shipments. No data are available to indicate MOP is present in other products above trace levels.

Ecological Effects (fish, daphnid, and algal toxicity).

Adequate existing data are available for these endpoints. A study detail needs to be provided in a number of the robust summaries.

Specific Comments on the Robust Summaries

Environmental Fate (photodegradation, stability in water, biodegradation, and transport/distribution).

Transport/distribution. The submitter needs to provide the in-put values for the fugacity calculation.

Ecological Effects (fish, daphnid, and algal toxicity).

The submitter needs to address the amount of solvent used in the studies.

Followup Activity

EPA requests that the Submitter advise the Agency within 60 days of any modifications to its submission.